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OCT 30 2001

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Date Prepared: August 12, 2001

1. Definition and Intended Use

The TM2000 EasyTrace Plus Transtelephonic Receiving Center system comprises a receiver, a PC with associated equipment, and a package of software tools.

The System is intended to support a remote monitoring, i.e. receiving, storing, displaying, measuring, updating, printing and re-transmitting of patient ECG and Spirometric parameters and other relevant data.

2. Device Class

The TM2000 EasyTrace Plus Transtelephonic Receiving Center system is classified as Class II medical device (21 C.F.R. Par. 870.2920 (1992)).

3. Applicable Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Act for telephone ECG and Spirometric transmitter devices.

TM2000 EasyTrace Plus meets the requirements of the following standards and guidances:

- EN1441: 1997 Medical Devices – Risk Analysis
- IEC 1025: 1990 Fault tree analysis (FTA)
- IEC/TR 513: 1994 Fundamental aspects of safety standards for medical electrical equipment
- IEC 801-1, 1984, "General Introduction"
- IEC 601-1, 1996, "Medical Electrical Equipment, General Requirements for Safety"
- IEC 601-1-1, 1996, "Safety Requirements for Medical Electrical Systems"
- IEC 601-1-4, 1996, "Part 1-4, Programmable Electrical Medical Systems"
- IEC 812: 1985 Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)
- IEC 300-3-9: 1995 Dependability management, Part 3: Application guide – Section 9, Risk analysis of technological systems
- "Reviewer Guidance for Computer Controlled Medical Devices", FDA Aug 29, 1991
- ISO/IEC Guide 51: 1990 Guidelines for the inclusion of safety aspects in standards
- ISO 9002 guidelines



- EN-46002
- IEEE Standard for Software Quality Assurance Plan
- FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998
- FDA's "New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial equivalence in Premarket Notifications" Final Guidance, CDRH, March 20, 1998.

4. Features

- Runs on any MS Windows operating system
- Manual entry of patient and physician detail
- Analog/digital (acoustic/modem) receiving or direct download via IR interface
- Data processing capabilities
- ECG and Spirometric event recording
- Receiving, viewing and printing medical data from Card Guard's transmitters
- Storage of up to 10 - 40 thousand transmissions (depending on transmitter type)
- Maximum database file size of 2 GB

5. User Interface

The TM2000 EasyTrace Service Plus GUI enables access to all categories of data through 3 built-in subsystems.

6. Substantial Equivalence

Card Guard hereby claims that the TM2000 EasyTrace Plus is substantially equivalent to Telemedicine 2000, the Transtelephonic Receiving Center, K992164

The proof of substantial equivalence in all that concerns the intended use, principles of operation, features and technological characteristics is provided in Chapter 7. *Substantial Equivalence to Cleared Devices.*

7. Design Controls and Hazard Analysis

The Card Guard's product design procedure, and QA and QC policy, formalize the design and production process and assure that all the respective requirements are met. In the framework of the Design Controls the testing was conducted to verify the system compliance with all its design specifications.

The device Level of Concern criteria were evaluated and the system was determined to be *a moderate level of concern system.*

The rigorous design evaluation and the System Safety and Risk analysis expose potential failures or possible system flaws which could directly or indirectly effect the patient.

8. Conclusions

The system constitutes a safe and reliable means for receiving, storing, displaying, analyzing, updating, printing and re-transmitting of patient ECG and Spirometric parameters and other patient related data.

Its operation present no adverse health effect or safety risks to patients when used as intended.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2002

Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
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ISRAEL

Re: K013175

Trade Name: TM2000 EasyTrace Plus Receiving Center
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: October 15, 2001
Received: October 17, 2001

Dear Mr. Gonorovsky:

This letter corrects our substantially equivalent letter of October 30, 2001, regarding the indications for use statement.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

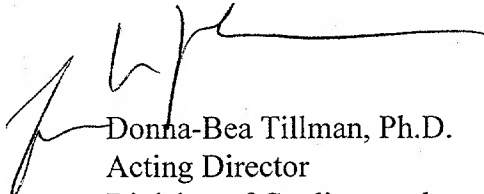
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,




Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

The TM2000 EasyTrace Plus Telemedicine Receiving Center is intended for supporting transtelephonic monitoring of Electrocardiography (ECG) and Spirometric parameters of patients.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K013175

✓ Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)